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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,694	06/15/2001	Jon Duvick	35718/208255 (5718-111C)	1574

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EXAMINER
IBRAHIM, MEDINA AHMED

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/882,694	Applicant(s) DUVICK et al
	Examiner Medina Ibrahim	Art Unit 1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Nov 27, 2002* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-33* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The response of 11/27/02 and Amendment B have been entered. New claims 21-33 have been added. Therefore, claims 1-33 are pending in this application and are under examination.

All rejections and objections not stated below have been withdrawn.

Claim Rejections - 35 USC § 112

2. Claims 1-20 remain rejected and new claims 21-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of reducing pathogenicity of a fungus producing fumonisin in a plant/plant cell by stably incorporating into the genome of a plant/cell the nucleotide sequence of SEQ ID NO:12, 14, 16, 18, 20, 22, 24, 26, 28, 30 or 32 encoding a polypeptide having fumonisin esterase and nucleotide sequence of SEQ ID NO:2, 4, 7, or 10 encoding a polypeptide having amine oxidase activity, a plant and plant cell stably transformed with said nucleotide sequences, does not reasonably provide enablement for a method that employs nucleotide sequences having at least 70%, 80%,or 90% sequence identity to NO:12, 14, 16, 18, 20, 22, 24, 26, 28, 30 or 32 and 90% or 95% sequence identity to SEQ ID NO:2, 4, 7 or 10 encoding a polypeptide that retains fumonisin detoxification activity, a plant and plant cells stably transformed with said nucleotide sequences. This rejection is repeated for the same reason as set forth in the Office action of 08/27/02.

Applicants' arguments filed 11/27/02 have been fully considered but are not deemed persuasive.

Applicants argue that the specification provides ample guidance for how to obtain nucleotide sequence having at least 70%, 80%,or 90% sequence identity to SEQ ID NO:NO:12, 14, 16, 18, 20, 22, 24, 26, 28, 30 or 32 and nucleotide sequences having at least 90% or 95% sequence identity to SEQ ID NO:2, 4, 7 or 10 that retains fumonisin detoxification activity. Applicants assert that the claimed nucleotide sequences vary from the disclosed sequences by structural parameters, and methods for determining said structural parameters are disclosed in the specification and are known in the art (pages 17-20). Applicants argue that assays for testing fumonisin degrading activity are also taught in the specification and are known in the art. Applicants assert that one who wishes to practice the invention would need 3 steps: a) to stably integrate into a plant or plant cell those primary nucleotide sequences that meet the claimed limitations. 2) stably integrate into the plant and plant cell those secondary nucleotide sequences that meets the claimed limitations and 3) to assay the transformed plant and plant cell for fumonisin detoxification activity. Therefore, given the ample guidance provided in the specification and the quantity of the experimentation necessary to practice a single embodiment of the invention, the instant invention is enabled as broadly claimed.

The Examiner maintains that the scope of the claims is broader than the enabling disclosure for the reasons set forth in the last Office action. Applicant has not

shown or provided sufficient guidance which region(s) in the disclosed nucleotide sequences can tolerate modifications that result the desired nucleotide sequences. The specification merely provides guidance for methods for altering single amino acid/base in a given protein/ nucleotide sequence to produce variants. However, no specific guidance has been provided as to where and how the disclosed sequences can be modified so as the resultant variants will retain both the structural and functional limitations recited in the claims. A mere recitation of structural and functional limitations in the claims, without any specific guidance as to how to make nucleotide sequence having the claimed structural and functional limitations to enhance fumonisin resistance, would not overcome the rejection. In addition, neither Applicants' response nor the state of art provides evidence that structural identity between sequences inherently implies functional identity, as stated in the last Office action.

Regarding Applicant's arguments against undue experimentation, it is note that while determination of sequence homology, and assays for testing fumonisin detoxification activity are known in the art and would require undue experimentation, making and testing all nucleotide sequences that meet both the structural and the functional limitations recited in the claims are not considered to be routine. These tests are considered undue experimentations, as stated in the last Office action. Absent any clear and convincing evidence as to why all nucleotide sequences having at least 70%, 80%, or 90% sequence identity to SEQ ID NO:NO:12, 14, 16, 18, 20, 22, 24, 26, 28, 30 or 32, and nucleotide sequences having at least 90% or 95% sequence identity to SEQ

ID NO:2, 4, 7 or 10 are expected to encode a polypeptide having fumonisin detoxification activity, the rejection may be maintained.

Written Description

Claims 1-20 remain rejected and new claims 21-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the same reasons of record as set forth in the last Office action. Applicants' arguments filed 11/27/02 have been fully considered but are not deemed persuasive.

Applicants assert that the recitation of 90% sequence identity is a predictable structure of the claimed nucleotide sequences, and that the description of a representative number of species does not require description of each species that the genus encompasses. Applicants argue that the claimed invention satisfies the written description requirement as evidenced by Example 14 of the Revised Interim Written Description Guideline. Applicant correctly states that according to Example 14, a single species of SEQ ID NO:3 is sufficient to provide adequate written description for the genus.

The Examiner maintains that rejection is proper given that the claims are broadly drawn to a method for reducing fumonisin pathogenicity by expressing nucleotide sequence having at least 90% and 95%,sequence identity to SEQ ID NO:2, 4, 7 or 10

and nucleotide sequences having at least 70%, 80%,or 90% sequence identity to SEQ ID NO:NO:12, 14, 16, 18, 20, 22, 24, 26, 28, 30 or 32 and encoding a polypeptide having fumonisin detoxification activity, and plants and plant cells stably transformed with said nucleotide sequences. While the recitation of 90% sequence identity is a predictable structure of the claimed nucleotide sequences, it is unpredictable whether any nucleotide sequence having said structure will encode a polypeptide having the desired function. Lazar et and Broun disclosed in the last Office action showed that 90% sequence identity is insufficient to predict function. With respect to Example 14 of the Revised Interim Written Description Guideline, the two situations are not analogous because the sequence identity of the instant application is based on a nucleotide sequence. Unlike Example14, the ability of any and all nucleotide sequences having 90%, 80, and 70% sequence identity to the disclosed sequence to encode a polypeptide that retains fumonisin detoxification activity is uncertain. Therefore, the Interim Written Description Guidelines does not appear to support Applicants' position. The rejection is maintained.

Remarks

The claims are free of the prior art of record.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (703) 306-5822. The Examiner can normally be reached Monday -Thursday from 8:30 AM to 5:30 PM and every other Friday from 9:00AM to 5:00PM

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

February 6, 2003
mai

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600